Five-Year Survival of Short Single-Tooth Implants (6 mm): A Randomized Controlled Clinical Trial

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Abstract: The aim of the present study was to evaluate whether 6-mm dental implants in the posterior segments of either jaw perform equally well in terms of clinical and radiographic outcomes when compared with 10-mm implants after 5 y of loading. Patients with single-tooth gaps in the posterior area who were scheduled for implant therapy were randomly assigned to a group receiving either a 6- or 10-mm implant. After a healing period of 10 wk, implants were loaded with a screw-retained single crown and followed up at yearly intervals. Of 96 patients, 86 could be recalled after 5 y. The implant survival rates amounted to 91% (95% confidence interval: 0.836 to 0.998) for the 6-mm group and 100% for the 10-mm group (P = 0.036). Median crown-to-implant (C/I) ratios were 1.75 (interquartile range [IQR], 1.50 to 1.90) for the 6-mm group and 1.04 (IQR, 0.95 to 1.15) for the 10-mm group, whereas the median marginal bone levels measured -0.29 mm (IQR, -0.92 to 0.23) for the 6-mm group and -0.15 mm (IQR: -0.93 - 0.41) for the 10-mm group after 5 y. The C/I ratio turned out to be statistically significant (P < 0.001), whereas marginal bone levels showed no significant difference between the groups. The 6-mm implants exhibited significantly lower survival rates than the 10-mm implants over 5 y, whereas there was no difference between upper and lower jaws in terms of survival (P = 0.58). Lost implants did not show any sign of marginal bone loss or peri-implant infection previous to loss of osseointegration. High C/I ratio and implant length had no significant effect on marginal bone level changes or technical and biological complications (German Clinical Trials Registry: DRKS00006290).

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5-year survival of short (6mm) single tooth implants –

A randomized, controlled clinical trial

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Abstract

The aim of the present study was to evaluate whether 6 mm dental implants in the posterior segments of either jaw perform equally regarding the clinical and radiographic outcomes compared to 10 mm implants after 5 years of loading. Patients with single tooth gaps in the posterior area scheduled for implant therapy were randomly assigned to a group receiving either a 6 mm or a 10 mm implant. After a healing period of 10 weeks implants were loaded with a screw-retained single crown and followed up at yearly intervals.

A total of 86 out of 96 patients could be recalled after 5 years. The implant survival rates amounted to 91%, (95%CI: 0.836, 0.998) for the 6mm group and 100% for the 10mm group (p=0.036). Median crown-to-implant ratio (C/I) calculated 1.75 (IQR:1.50-1.90);(6mm group) and 1.04 (IQR:0.95-1.15);(10mm group), whereas the median marginal bone levels measured --0.29 mm (IQR:-0.92-0.23);(6mm group) and-0.15 mm (IQR:-0.93-0.41);(10mm group) after 5 years. The C/I –ratio turned out to be statistically significant (p<0.001), whereas marginal bone levels showed no significant difference between the groups.

The 6mm implants exhibited significantly lower survival rates compared to the 10mm implants over 5 years, whereas there was no difference between upper and lower jaw regarding survival (p=0.58). Lost implants did not show any sign of marginal bone loss or peri-implant infection previous to loss of osseointegration. High C/I-ratio and implant length had no significant effect on neither marginal bone level changes nor on technical and biological complications.

Introduction

Today dental implants are considered a safe and reliable treatment for replacing missing teeth (Albrektsson et al. 2012; Benic et al. 2017; Jung et al. 2008; Jung et al. 2012). There is broad evidence attesting high survival rates for both the implant and the respective implant-supported prosthesis with single crowns (Jung et al. 2012; Pjetursson et al. 2014; Sailer et al. 2015). Nevertheless, efforts are constantly made towards improving implant therapy and reducing invasiveness. As implant survival is reported to reach 97.2% after 5 years and 95.2% after 10 years (Benic et al. 2017; Blanes et al. 2007; Jung et al. 2012), the focus has shifted from investigating not only survival rates but additional factors such as success rates, reducing patient morbidity, shortening of the treatment time and lowering the total cost of treatment. This has led to the use of fewer implants with smaller diameters and shorter implants over the last decade. These types of implants have many objective advantages. They mainly allow for less invasive interventions. They can thus minimize the risk of harming neighboring anatomic structures, accelerate preparation of the implant bed and demand less need for remaining vertical bone height (Pistilli et al. 2013; Thoma et al. 2015a). Accordingly, they might be a reasonable alternative to the use of standard-length implants (Esposito et al. 2011; Thoma et al. 2015b). In general, shorter implants are reported to reach high survival rates (Lai et al. 2013; Slotte et al. 2015; Telleman et al. 2011). Despite that the term 'short' is not clearly defined and may include implants of lengths up to 11mm, within the present publication the term 'short' refers to a previously published systematic review and an implant length of ≤8 mm (Renouard and Nisand 2006).

Although shorter implants tend to exhibit increased crown-to-implant ratios (C/I), this is not reported to have an influence on biological complications or implant failure rate (Quaranta et al. 2014). Furthermore, it has been reported that high C/I-ratios do not have an influence on marginal bone loss compared to implants with lower C/I-ratios (Blanes 2009; Schneider et al. 2012). In consequence, the use of short implants is growing. They reduce the necessity of invasive pre-treatments such as primary vertical bone augmentation in the mandible.

Additionally, they also seem to be a viable alternative for the treatment of the single-tooth gaps in the maxilla (Pohl et al. 2017). Today there is scarce clinical evidence from randomized clinical trials (RCTs) regarding single, non-splinted prostheses supported by short implants in posterior sites'.

Thus, the aim of the present study was to investigate whether 6mm implants used for the prosthetic rehabilitation of single tooth gaps in the posterior area of both jaws would result in similar survival rates, marginal bone level changes as well as technical and clinical outcomes compared to 10mm implants. The hypothesis of the present study was that short implants would perform equally regarding clinical and radiographic parameters compared to implants of 10 mm length.

Materials and Methods

Study design

This study was designed as a randomized controlled 2-center clinical trial following the CONSORT guidelines regarding the design and conduct of an RCT and encompassed a total of 94 patients. The study protocol had been approved by the local ethical committee (StV Nr. 07/13). Patients were informed verbally and signed a written consent before being included in this study. Randomization was performed according to a computer-generated randomization list.

Patients eligible for implant therapy had to be older than 18 years of age and be able to comply with study procedures. Furthermore, patients had to be healthy regarding their periodontal (no probing depths exceeding 5 mm) and systemical status. A single tooth gap had to be present in the posterior segment (premolar or molar region) in the upper or lower jaw. Extractions had to be performed at least 6 months before implant placement and antagonists (teeth or implant) had to be present. A minimum amount of keratinized gingiva of 2mm and sufficient vertical amount of bone (6 mm in the maxilla, 10 mm in the mandible) had to be present at the future implant site. Internal sinus floor augmentation (Summers technique) could be performed if needed, but no lateral bone augmentation was allowed. Details regarding exclusion criteria were described in a previous publication (Sahrmann et al. 2016). In short, they comprised of the following: general contraindications against surgical interventions; smoking of more than 19 cigarettes per day (Lang and Tonetti 2003); insufficient oral hygiene; inadequate compliance to the study procedures; prior therapeutic radiation of the jaw, severe bruxism or clenching habits; any mucosal disease; preceding lateral bone augmentation with radio-opaque filler materials.

Surgical intervention

Implants were placed between March 2008 and November 2010 at two clinics (Periodontology and Prosthetics) at the University of Zurich by experienced surgeons. Local anaesthesia

(Septanest 1:200’000; Septodont, Niederkassel, Germany or Rudocaine Forte, Streuli Pharma AG, Uznach, Switzerland) was administered and a full thickness flap was raised.

1. 6mm group

   Standard Plus Tissue Level Implant, diameter 4.1 mm, length 6 mm, SLActive (Institute Straumann AG, Basel, Switzerland).
2. 10mm group

   Standard Plus Tissue Level Implant, diameter 4.1 mm, length 10 mm, SLActive, (Institute Straumann AG, Basel, Switzerland).

Implants were inserted according to the manufacturers guidelines. All implants had to reach a minimum stability of 20 Ncm. Healing abutments were inserted and single interrupted non-resorbable sutures (Supramid, B.Braun Medical AG, Sempach, Switzerland or Gore, Flagstaff AZ, USA) were used to adapt the wound margins. All implants were placed according to a non-submerged, one-stage surgical protocol.

Patients were instructed to refrain from mechanical cleaning at the surgical site. They were administered a 0.2% chlorhexidin solution to be used for rinsing (Kantonsapotheke Zurich, Zurich, Switzerland) two times a day for one minute until suture removal. No antibiotics were administered, but analgesics were at each patient’s disposal for use if needed (Mefenacid 250 mg/500 mg for max 1000 mg/day, Kantonsapotheke Zurich, Zurich, Switzerland). Suture removal was performed after 7-10 days and patients were re-instructed regarding their oral hygiene procedures.

Prosthetic procedure

Eight weeks after implant placement, a conventional impression was taken (Permadyne, 3M ESPE, Rüschlikon, Switzerland). Ten weeks after implantation, screw-retained implant crowns (SC) were inserted with a torque of 35 Ncm. A baseline clinical examination was performed and a single tooth radiograph obtained to serve as baseline data.

Follow up

Clinical examination

Patients were examined at baseline and recalled once a year after insertion of the SC. These follow up-visits were performed by one examiner at each clinic. The examination included the acquisition of the following clinical parameters: Probing Depth (PD), Bleeding on Probing (BOP), Plaque Index (PI). These measurements were performed at six sites per implant and at the adjacent teeth. Furthermore, photographs were taken and technical complications such as screw-losenings or chippings were recorded. A standardized single tooth radiograph was obtained at baseline and at each follow-up examination. Patients received an oral hygiene re-instruction, calculus removal and polishing of all tooth surfaces based on their individual needs.

Radiographical evaluation

The previously obtained radiographs from the 1- and 3-year follow had been digitized for evaluation for the previously published 3-year data (Sahrmann et al. 2016). At the 5-year follow up standardized digital radiographies were obtained again using the individualized radiograph trays. Subsequently the radiographs were evaluated applying an image processing software (ImageJ 64, National Insitute of Health, Bethesda, Maryland USA) and calibrated using thread distance and implant length. Measured parameters included first bone-to-implant (BIC) at the mesial and distal aspect of each implant; bone level at the adjacent teeth (first bone-to-tooth contact and cemento-enamel junction); crown length (longest vertical distance of framework of single crown reconstruction) measured from the implant shoulder to the top of the framework. Fig.1 Radiographs were assessed by one single calibrated examiner (VS). After marking the respective first coronal (BIC) contacts on the radiographs a consensus had to be reached between the authors NN and PS and all results were cross-checked with the above mentioned examiner. All predetermined distances were measured and crown-to-implant ratio was calculated.

Statistical analysis

As part of the design of this study a sample size calculation had been performed. Using a significance level α = 5% and assuming a standard deviation of 0.5 mm for each group, a two-sample t-test with 28 patients per group has 80% power to detect a potential difference in bone loss of 0.38 mm (Roccuzzo et al. 2010). With regard to a planned follow-up period of 10 years and accounting for dropouts, a minimum initial number of 45 participants per group were considered reasonable.

Marginal bone level changes as well as other quantitative technical and clinical outcome parameters were analyzed using the Wilcoxon rank sum test to detect statistical differences between the 6mm and the 10mm group. Categorical parameters between the groups were analyzed using the Fisher test while intra-group changes over time were analyzed using the Wilcoxon signed-rank test. Differences in survival between the groups were assessed by the Kaplan-Meier-estimator in combination with the log-rank test. The significance level was set to α=0.05 and the entire statistical analyses was performed with R (R Core Team 2015) including the survival package (Therneau 2015).

Results

A total of 86 patients (n=40; 6mm group)(n=46; 10mm group) out of the original 96 patients were recalled after a mean observation time of 5.1 ± 0.7 years. Patients (47 female; 39 male) had a mean age of 58.2 years (SD=12.8 y) at the time of recall. Patients in the 6mm group had a median age of 56.0 years and patients in the 10mm group 57.0 years, which did not turn out to be statistically significant. Out of seven patients from the 6mm group three were lost to follow up and four implants were lost over the course of the study. In the 10mm group one patient was lost to follow up. These patients had moved away and could not be reached anymore (for details see 'participant flow'). 36 patients (n=22; 6mm / n=14; 10mm) had a history of periodontitis. Ten sites in the maxilla (8 PM; 2 M) and 24 sites in the mandible (10 PM; 14 M) had received a 6mm implant. Whereas seventeen 10mm implants replaced 17 maxillary (10 PM; 7 M) and 19 mandibular (5 PM; 14 M) teeth.

All implants in the 10mm group were still in function at the 5-year follow-up, whereas four implants had been lost in the 6mm group, resulting in a survival rate of 100% for the 10mm group and 91%, (95%CI: 0.836, 0.998) for 6mm implants (Fig.2). The difference regarding survival was statistically significant between the groups (p=0.036). One of the short implants was lost after 2 years (mandibular molar site), whereas three implants were lost during the fourth year of follow-up (two mandibular molar and one maxillary premolar site). One of these patients was a moderate smoker (mandibular molar site), while two patients had a history of periodontitis (mandibular molar site). All of the four 6mm implants were lost without any previous detectable radiographic peri-implant bone loss. At the time of implant loss the patients had called in to say that the implant complex felt loose and that they felt pain whilst chewing. On clinical inspection all implants had lost osseointegration and could be removed by hand.

A low number of technical complications (such as minor chipping and screw-loosening) have been observed during the study period. All of these complications were solved chair-side and did not influence the biological complication nor the survival rate.

The residual height of the bone in the maxilla measured between 8mm and 16mm in all included patients. If a sinus floor elevation had to be performed according to the randomization, only the transcrestal approach (Summers Technique) was allowed. No patient dropped out because this could not be achieved. A total of 17 maxillary sites had received a 10mm implant. Of these, seven implants had been placed in native bone and 10 implants were placed with a Summers Technique. In these 10 sites an internal sinus floor augmentation of 1-2mm was performed.

A total of 72 patients (n=36 in each group) could be evaluated for the clinical parameters. Regarding probing depth (PD) twelve implants in the 6mm group (n=7 in one site; n=5 in two sites/implant) and 8 implants in the 10mm group (n=7 in one; n=2 in two; n=1 in three sites/implant) showed sites with a probing depth of ≥5mm. No implant displayed peri-implantitis in terms of pocket depths >5 mm in combination with suppuration and/or progressive marginal bone loss. Bleeding-on-probing (BOP) was measured at more than three sites per implant in two implants in each group. Twenty-one patients (N=11: 6mm; N=10: 10mm) were smokers (between 10 and 20 cigarettes/day). At the 5-year follow-up no significant differences between the groups were found regarding clinical parameters.

Radiographic evaluation

The median bone level change over time was moderate in both groups. In the 6mm group it proceeded from -0.18 mm (IQR:-0.59-0.14) at baseline, to -0.35 mm (IQR:-0.87-0.04) at 3 years, whilst measuring -0.29 mm (IQR:-0.92-0.23) after 5 years. The respective values in the 10mm group measured -0.06 mm (IQR:-0.61-0.16) at baseline, -0.33 mm (IQR:-0.86-0.25) at 3 years and -0.15 mm (IQR:-0.93-0.41) after 5 years. Values after 5 years of loading did not show significant differences between the groups. Fig.3

The median C/I ratio measured 1.75 (IQR: 1.50-1.90) in the 6mm group and 1.04 (IQR: 0.95-1.15) in the 10mm group, showing a statistically significant difference between both groups ($p<0.001$).

Discussion

The results of the present randomized, controlled clinical study demonstrated that:
i) 6 mm implants had a slightly lower survival rate compared to 10 mm implants over 5 years; ii) the marginal bone levels and their change over time evolved similar in both groups; iii) both groups showed similar results regarding biological parameters.

In general, available data on short implants reports similar survival rates for short (≤8 mm) implants compared to longer implants (Lai et al. 2013; Mezzomo et al. 2014; Rossi et al. 2015; Telleman et al. 2011). Compared to the use of longer implants in augmented sites, several authors concluded that the use of short implants might be the preferable method for both atrophic mandibular and maxillary regions (Esposito et al. 2011; Pistilli et al. 2013; Thoma et al. 2015b).

Only a limited number of clinical studies have investigated implants with a length of 6 mm or less for single-tooth prosthetic rehabilitation. Furthermore, only few publications exist regarding randomized, controlled clinical trials (RCT) (Pohl et al. 2017; Rossi et al. 2016; Sahrmann et al. 2016). Whereas the first publication reports results from a multi-center RCT examining only the posterior maxilla, the two latter studies investigated 6mm implants in both jaws applying an almost identical treatment protocol.

The results regarding implant survival in the current study contradicted the hypothesis that 6 mm implants would perform equally compared to implants of 10 mm length regarding survival. The obtained results seem to be confirmed by previously published results employing the same type of implant and very similar study procedures (Rossi et al. 2016). Authors reported lower survival rates reaching 86.7% for 6mm and 96.7% for 10 mm implants over a follow-up period of 5 years as opposed to the current study resulting in survival rates of 91% (6mm group) and 100% (10mm group). In the first study, one short implant was lost before loading, whereas three 6mm implants were lost after loading. All four implants were included in the calculation

for the survival rate. If only the loaded implants would have been accounted for, the survival rate would have reached 89% for the 6mm implants. The respective survival rates reported in the two studies can thus be interpreted similarly. Both studies report on 5-year data encompassing a total of 60 implants in 45 patients (Rossi et al. 2016) and 86 implants in 86 patients in the current study. A total of four short implants were lost in the current RCT after 2 years of loading. Three of these implants had been placed in the mandible, whereas in the study by Rossi et al. three out of four implants that were lost had been placed in the maxilla. Both studies did not show significant differences in implant loss regarding their allocation (upper or lower jaw). A possible explanation for the differences in implant loss might lie in different implant surfaces and loading protocols used in the two RCTs. Whereas in the current study implants with an SLActive surface were left to heal for 8 weeks before taking an impression, implants in the latter study had an SLA surface and were loaded 7 weeks after placement. Overall, the results are in congruence with the existing literature on short implants. The available literature does not report differences regarding survival rates for short implants placed in the upper or lower jaw (Lai et al. 2013; Lemos et al. 2016; Mezzomo et al. 2014; Telleman et al. 2011).

A recently published multi-center RCT reported a 100% survival rate after 3 years of loading for both 6 mm implants without sinus floor augmentation and longer (11-15mm) implants placed in the edentulous posterior maxilla with simultaneous lateral sinus augmentation (Pohl et al. 2017). Additionally, a prospective clinical trial on consecutively placed 6mm implants of the same type as used in the present study reported a survival rate of 100% after an observation period of 5 years (Rossi et al. 2015). These results stand in contrast to the 5-year results of an RCT investigating the same type of implant published by the same author (Rossi et al. 2016) as well as to the results from the present study.

Although some implants did exhibit probing depths of ≥5mm at mostly isolated sites, no periimplantitis (Lang et al. 2011) was diagnosed at all since enhanced pocket depth was not associated with bleeding-on-probing, suppuration or progressive marginal bone loss.

Although the C/I-ratio turned out to be statistically significant between the investigated groups, it did not have an influence on the overall complication rate or on marginal bone level changes. These results are in congruence with previously published data (Blanes 2009; Schneider et al. 2012)

All 6mm implants that were lost in the course of the study did so without clinically or radiographically detectable bone loss. The clinical situation after removal of the implants presented with a clearly defined bony cavity that was lined with soft tissue all the way to the apical portion. A separate assessment of the obtained radiographs of the current study resulted in pronounced radio-opacity at the 6mm implants (Sahrmann et al. 2017). Whether this finding might be related to spontaneous implant exfoliation remains to be investigated. These so-called spontaneous implant losses have been explained with possible micro-fractures of the peri-implant bone, e.g. the break-up of a formerly established osseointegration (Rossi et al. 2016). Another possible explanation might be implant loss caused by overload as demonstrated in a pre-clinical study and histomorphometric analysis (Isidor 1997), where implants were found to be completely lined by connective tissue after vast forces had been applied. In contrast, several authors could not confirm an association of loss of osseointegration and occlusal overload (Gotfredsen et al. 2001a; 2001b; 2002; Heitz-Mayfield et al. 2004; Ogiso et al. 1994). Thus, regarding overload the available literature is contradictory and still inconclusive. While all of the cited publications are based on pre-clinical models, studies on the clinical long term use of short implants exposed to high relative load might bring new insights to this discussion.

Conclusion

The results of this study support the use of 6mm single implants as a reasonable alternative to implants of standard length. Eventhough shorter implants resulted in a slightly minor survival rate of 91% compared to 100% for 10mm implants over the period of 5 years. Long-term data on the clinical performance of short (≤8 mm) implants is still lacking and thus needed.

Author Contributions

N. Naenni contributed to data analysis, interpretation and drafted the manuscript. P. Sahrmann contributed to conception and design, data acquisition and drafted the manuscript. P.R. Schmidlin contributed to conception and design, data acquisition and critically revised the manuscript. D.B Wiedemeier contributed to data analysis and visualisation and critically revised the manuscript. V. Sapata contributed to data analysis. T. Attin, C.H.A. Hämmerle and R.E. Jung contributed to conception and design and critically reviewed the manuscript.

Acknowledgements and conflict of interest

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Figure legends

Figure 1. Radiograph with the respective lines regarding the measurements for the first bone-to-implant contact (BIC) and the level of the bone as well as the cement-enamel junction at the adjacent teeth. A additional line was drawn along the implant shoulder. Perpendicular to this, the known implant length (a) was used to calibrate the radiograph. The length of the crown (b) was measured as the distance from the implant shoulder to the most coronal point of the framework. This allowed for the calculation of the Crown-Implant-Ratio (C/I).

Figure 2. Implant survival rate over time (Baseline-5years) for the 6 mm and the 10 mm group according to Kaplan-Meier Analysis. Dashed lines show the 95 % confidence interval.

Figure 3. Marginal bone levels (mm) at Baseline and at the 5-year follow-up for the 6 mm group and the 10 mm group (p=0.57).

Tables and Figures

Fig 1

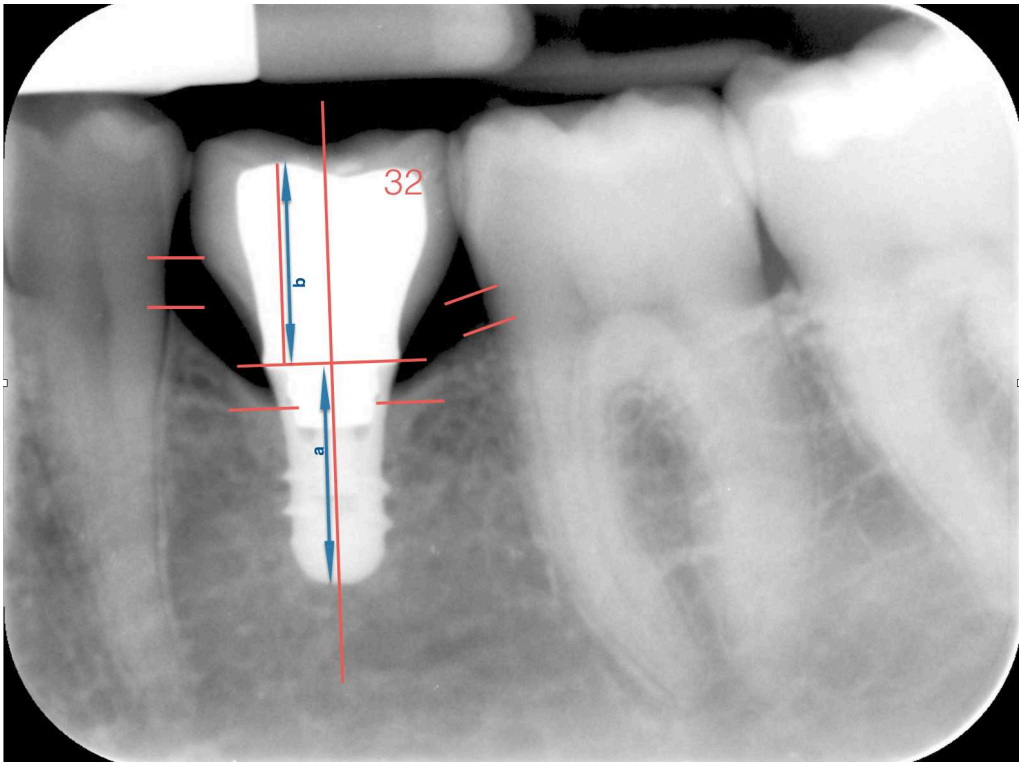


Fig 2

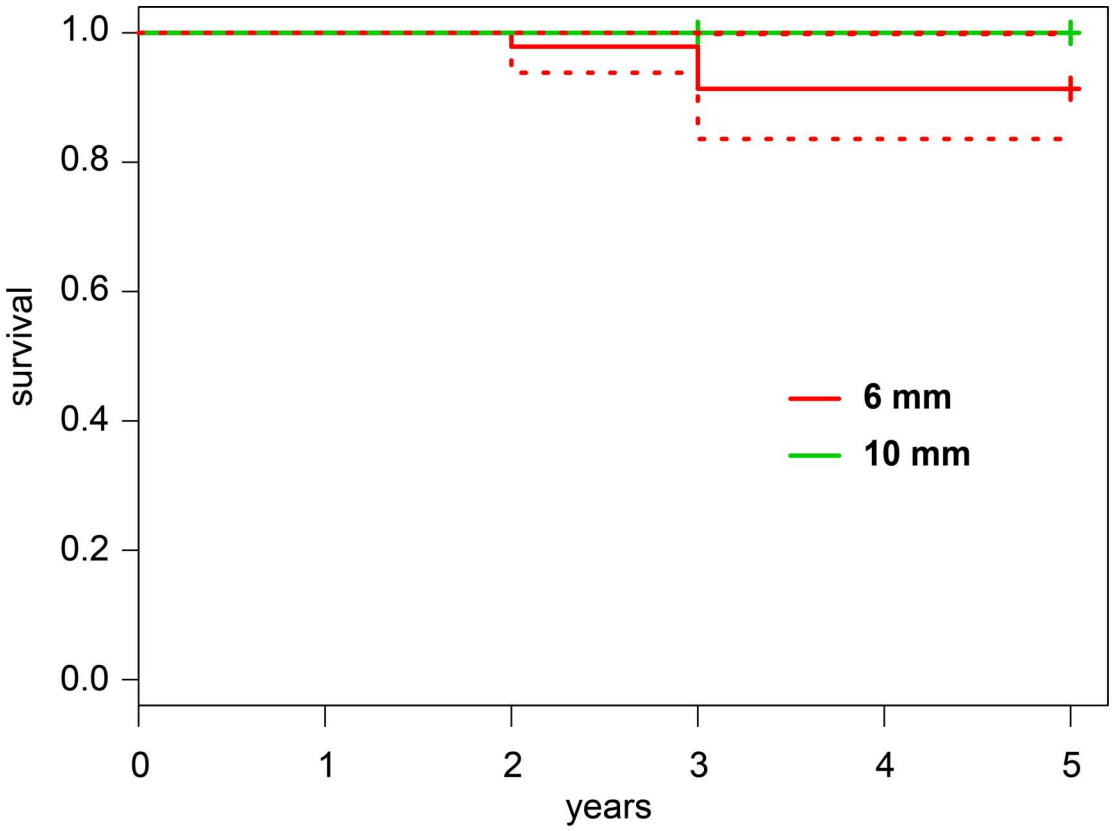
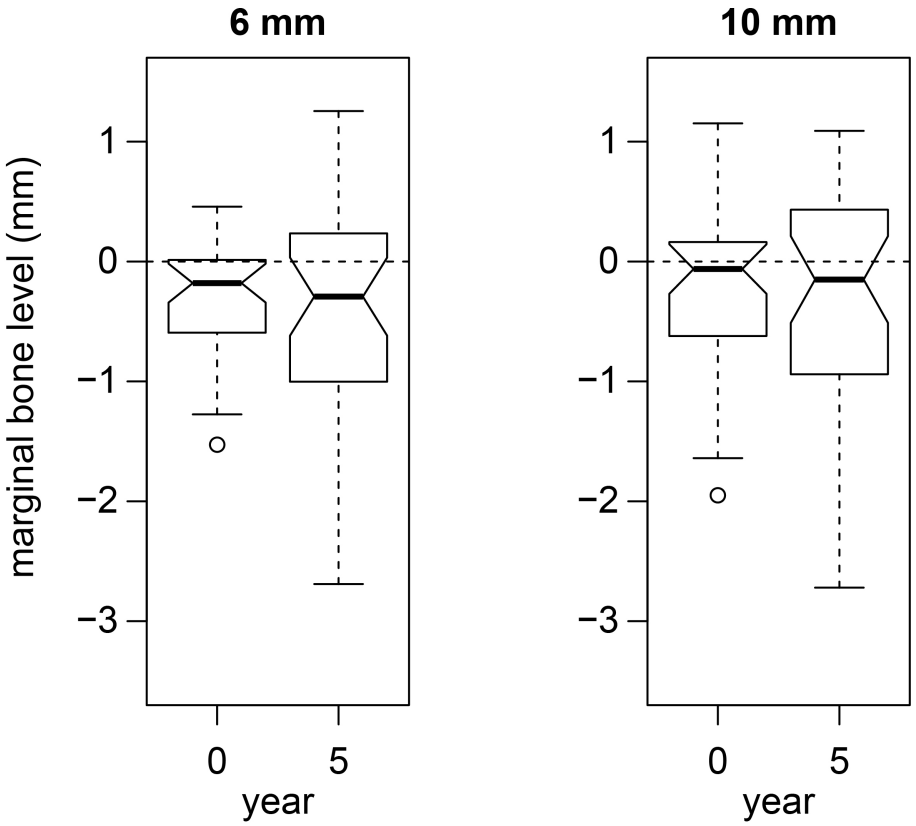

1.0
0.8
0.6
0.4
0.2
0.0
survival
0
1
2
3
4
5
years
6 mm
10 mm

Fig 3


6 mm
10 mm
marginal bone level (mm)
1
0
−1
−2
−3
0
5
year